REMARKS

Applicant acknowledges the courtesy shown by the Examiner in charge of the present application in granting and holding an interview with Applicant's undersigned attorney on 22 August 2006. During the interview, Applicant's undersigned attorney advised the Examiner of co-pending applications that relate to ribavirin compositions. These applications are also identified on an Information Disclosure Statement submitted herewith. The merits of the Official Action mailed 23 February 2006 was also discussed. In particular, Applicant agreed to resubmit the drawing in the application because the drawing currently in the case was poorly scanned. It was not clear what had occurred with the amended drawing, which Applicant submitted in its Preliminary Amendment on 28 January 2004. Applicant further agreed to update the continuity data for the present application. It was further agreed that Applicant would reply to the Official Action in writing and submit amendments and arguments.

Claims 39-58 are currently pending in the present application. Claims 1-38 have been canceled without prejudice or disclaimer thereto and claims 57–58 are new. Accordingly, claims 39-58 are currently under consideration.

Support for new claims 57 and 58 can be found throughout the originally filed application including, for example, original claims 2 and 3 and in tables 1 through 3.

Claims 39, 42, 43, 47, 48, 49, 51, 52 and 54-56 have been amended. Support for these amendments can be found throughout the originally filed application including, for example, on page 3, beginning at line 25 of the specification where Applicant describes a process which includes mixing ribavirin with *one excipient* as well the original claims and tables in the specification. Accordingly, it is respectfully submitted that the new claims and claim amendments do not raise any new matter issues.

Drawing

Applicant has resubmitted the formal drawing in the present application. Accordingly, reconsideration of the objection to the drawing in the application is respectfully solicited.

Continuity Data

As requested by the Examiner, Applicant has amended the specification to update the continuity data of the present application. Accordingly, reconsideration and withdrawal of the objection to the specification is respectfully solicited.

35 U.S.C. §112, 1st

Claims 39-56 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written descriptive support. The rejection is traversed and reconsideration is respectfully solicited.

Claims 39-56 are fully supported by the original application. As noted in Applicant's Preliminary Amendment, claim 39 is supported, for example, by the disclosure on page 3, beginning at line 15 and on page 6, Table 3, where Applicant discloses example formulations including the addition of water in the range of 15-79% of the total mixture. Claims 40 and 41 find support from at least original claims 30-15 and 21. Claims 42-43 find support throughout the specification and tables and claim 44 finds support from original claims 2, 3, 6 and in the tables of the specification. Claims 45 and 46 find support from original claims 11, 13, 20 and at least on page 9, lines 15-16 of the specification. Claims 47-48 recite subject matter disclosed on page 3, beginning at line 15 and in Table 2, where Applicant discloses an example formulation including two excipients. Claims 49-53 also find support in the original application as discussed above. In addition, claims 51 and 53 find support from the Abstract of the original application where Applicant discloses preparing pharmaceutical dosages of ribavirin mixtures and claims 54-56 find

additional support on page 1, beginning at line 21 and page 3, beginning at line 15 where Applicant describes the advantages of formulating ribavirin mixture by wet granulation.

Accordingly, it is respectfully submitted that claims 39-56 are fully supported by the originally filed application and that those of ordinary skill in the art would have recognized that the inventor had possession of the claimed subject matter at the time of the filing of the original application.

In the Office Action, the Examiner asserted that a patent is granted in return for a disclosure of :all of the details of an invention" and cited to *Brenner v. Manson*, 148 USPQ 689 (S. Ct. 1966) at 696. Applicant respectfully submits that the standard applied by the Examiner is not the standard for written description. Written description does not require that an Applicant disclose all the details of an invention. In fact, under the enablement standard, the Courts have held that a patent need not teach, and *preferably omits* that which is well known in the art. *In re Buchner*, 18 USPQ 2d 1331, 1332 (Fed. Cir. 1991); MPEP § 2164.01. Moreover, Brenner does not relate to written description, but rather to Supreme Court judicial authority and the issue of utility. In Brenner, the Court held that utility of a compound must be provided for an application to comply with 35 U.S.C. §101. Brenner is not applicable to the present application. Applicant has described the utility of ribavirin compositions in the present specification. It is a broad spectrum anti-viral and, in particular, has utility for the treatment of Hepatitis C viral infections. See page 1 of the specification. Accordingly, the utility of ribavirin compositions and the processes therefore fully comply with 35 U.S.C. §101.

Thus, the standard for written description is whether one of skill in the art would recognize Applicant had possession of the now claimed subject matter. Applicant has identified where

support can be found for each of the claims. Accordingly, reconsideration and withdrawal of the rejections are respectfully solicited.

35 U.S.C. §112, 1st

Claims 39-56 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed and reconsideration is respectfully solicited.

Undue or unreasonable experimentation is not needed to practice the presently claimed subject matter, particularly since Applicant provides general guidance and specific working examples in the original application.

Independent claim 1 is directed to a process of forming ribavirin particles and include the steps of mixing ribavirin with an excipient to form a mixture, adding water to the mixture and shaping the mixture into particles. These steps are not particularly complex in light of Applicant's disclosure and in light of the level of skill in the pharmaceutical arts. As an example of the level of skill, Applicant points to the Runick and Porter references cited by the Examiner in the Official Action.

Independent claims 47, 49 and 51 are directed to a process of forming a ribavirin *mixture* while each of these claims recite different steps, they generally include combining ribavirin with another ingredient. Applicant respectfully submits that combining ribavirin with various ingredients to form a *mixture* is not particularly complex nor difficult in light of the guidance provided by the specification and the level of ordinary skill in the pharmaceutical arts.

Independent claim 54 is directed to a process of formulating a ribavirin composition including the steps of wet granulation and drying and independent claim 55 is directed to a ribavirin composition in the form of free flowing particles. Once again, Applicant respectfully submits that

the practice of these claims is not particularly complex given the guidance provided by the application and the level of skill in the pharmaceutical arts.

In the Office Action, it was asserted that the scope of the claims were excessive in light of the specific embodiments provided in the present application and that the claims failed to define the number of, or the particular identities of, the excipients in the claims which allegedly rendered them non-enabled. Applicant respectfully traverses these assertions.

While there appears to be no dispute that Applicant has provided working examples and specific embodiments on how to practice the claimed subject matter, Applicant does not agree that its claims must be limited to its specific embodiments. The test for enablement is whether one of ordinary skill in the art can make and use the claimed subject matter without undue experimentation. See, e.g., *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). As noted above, Applicant has shown that the nature of this invention relates to the pharmaceutical formulation arts and the level of skill in that art is provided by at least the references cited by the Examiner. Those references show that those of skill in the art are knowledgeable about formulating pharmaceutically active ingredients with excipients. These references further show that the pharmaceutical arts is a relatively mature art and that the level of predictability for selecting a particular excipient with a pharmaceutically active compound involves relatively little experimentation. Moreover, Applicant provided several working examples in its specification. The claims are relatively easy to practice. Accordingly, it is respectfully submitted that one of ordinary skill in this art would undertake little, if any, experimentation to make a ribavirin particle or ribavirin mixture as claimed. Reconsideration and withdrawal of the rejection are respectfully solicited.

35 U.S.C. §112, 2d

Claims 39, 43, 47, 51, and 54-56 were rejected under 35 U.S.C. §112, second paragraph, as allegedly lacking definiteness. The rejection is traversed and reconsideration is respectfully solicited.

Claim 39, 43 and 49 were rejected because they recited the expression "at least three excipients" or "at least two excipients". According to the Examiner, these expressions rendered the claims incomplete because the identity of the excipients was not provided and because the upper limit of the number of excipients was not specified. Applicant traverses this assertion.

Those of skill in this art understand the term "excipient" and the terms "at least two" and "at least three" excipients in a pharmaceutical mixture. See, e.g., the art cited in the Official Action. The term is ubiquitous in the pharmaceutical arts. Clearly, those of skill in the art understand the metes and bounds of the terms of the claims. Rather, it appears that the Examiner's argument for concluding indefiniteness is based on breadth. Assuming, arguendo, that the claims are broad, it is black-letter law that the breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear and if Applicants have not otherwise indicated that they intend the invention to be a scope different from that defined in the claims, then the claims comply with 35 USC 112, second paragraph. *Id*; see also, MPEP 2173.04. Accordingly, reconsideration and withdrawal of the rejection are respectfully solicited.

Claim 54 was considered indefinite because the claim allegedly failed to provide any steps. The assertion is traversed. The claim recited that formulation was formulated by wet granulation. The step recited was formulating by wet granulation. Nevertheless, Applicant has

amended claim 54 to recite a wet granulation step and a drying step. Reconsideration and withdrawal of the rejection are respectfully solicited.

Claim 55 was considered incomplete because it allegedly failed to identify the substances that make-up the ribavirin composition. The rejection is traversed and it is respectfully submitted that one of ordinary skill in the art would have no difficulty understanding the meets and bounds of the claim. Nonetheless, Applicant has amended the claim to recite that the composition comprises ribavirin and am excipient. Reconsideration and withdrawal of the rejection are respectfully solicited.

Double Patenting

Claims 39-54 were rejected under the doctrine of obviousness-type double patenting over claims 1-17 of U.S. Patent No. 6,720,000. The rejection is traversed. Nonetheless, Applicant respectfully requests that this rejection be held in abeyance until allowable subject matter is identified.

35 USC 103

Claims 39-54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tam '097 in view of Liebowitz and further in view of Rudnic and Porter. The rejections are traversed and reconsideration is respectfully solicited.

Independent claim 39 is directed to a process of forming ribavirin particles. The process comprises: mixing ribavirin with an excipient to form a mixture; adding water to the mixture in the range of 15-79% of the total mixture; and shaping the mixture into ribavirin particles. Dependent claims 40-46 further define aspects of the process.

Independent claims 47, 49 and 51 are directed to a process of forming a ribavirin mixture. While each claim recites different steps, the claims generally include combining ribavirin with an excipient and adding water. Dependent claims 48, 50, 52-53 and 57-58 recite further aspects of the process.

Independent claim 54 is directed to a process of formulating a ribavirin composition comprising the steps of wet granulation and drying and independent claim 55 is directed to a ribavirin composition comprising an excipient and in the form of free flowing ribavirin particles.

In contrast, Tam does not disclose, teach or suggest any process steps for the preparation of any pharmaceutical composition. Tam simply establishes that ribavirin compositions were known prior to Applicant's application.

Liebowitz, a secondary reference, teaches a process using "dry" compaction. (See, e.g., column 1, lines 30-34; column 1, line 52; column 4, beginning at line 65, the section titled "Manufacturing Procedure".) Liebowitz recognizes many processing difficulties in preparing ribavirin compositions, including flowability, uniformity, etc. (See, e.g., column 1, lines 15-29). However, to solve these processing difficulties, Liebowitz teaches a process that explicitly excludes a wetting agent.

In many respects, the Liebowitz process is the opposite of the claimed process. There is no teaching or suggestion anywhere in Liebowitz relating to the use of a wetting agent, as recited by claim 54, let alone adding water to a ribavirin mixture, as recited by claims 39-53 and 57-58.

Moreover, there is no teaching or suggestion in Liebowitz of a drying step, as recited by claims 47-54. The lack of this step is not surprising since Liebowitz never suggests wetting its mixture in the first instance.

Hence, the combination of Tam and Liebowitz would not motivate one skilled in the art at the time to arrive at the presently claimed subject matter. Tam has nothing to do with the preparation of ribavirin compositions and Liebowitz teaches preparation steps that are the opposite of the present process claims. Accordingly, it is respectfully submitted that the combination of Tam and Liebowitz not only fails to reach the presently claimed process but, in fact, teaches away from it.

The additional secondary references do not cure the deficiencies of Tam and Liebowitz. Rudnic relates to general production methods for preparing oral solid dosage forms and Porter teaches general techniques for applying coatings to solid dosage forms.

The secondary references teach dry and wet processes. They teach ingredients for fast dissolving and sustained release formulations. They teach nothing specifically regarding the preparation of a ribavirin composition and there is no reason why one of ordinary skill in the art at the time would pick and choose among the general teaching of these secondary references to arrive at the presently claimed subject matter.

Indeed, Liebowitz has already taught a process that allegedly solves many of the art recognized difficulties of preparing ribavirin solid dosage forms. Hence, those skilled in the art would be motivated to follow the dry compacting process of Liebowitz. Given the problems associated with ribavirin formulations, as identified by Liebowitz, it is respectfully submitted that one of skill in the art would not expect success in practicing the opposite of what Liebowitz teaches.

Moreover, Applicant respectfully submits that there are secondary indicia of non-obviousness to its claimed subject matter. Ribavirin is a known antiviral drug and its compositions have been known since the mid-1970's. See, e.g., U.S. 3,927,216 to Witkowski,

column 4, beginning on line 53. However, despite the fact that ribavirin compositions have been known since the 1970's, only recently has the art discovered the benefits of using a wet process to prepare ribavirin compositions.

Indeed, in subsequently filed continuation patents (U.S. 6,335,032 B1 and U.S. 6,337,090 B1) to Liebowitz 5,916,594, declarations were submitted to the Patent Office conceding that without the use of water, the dry process of Liebowitz failed to achieve flowable particles permitting the manufacture of tablets of consistent weight. (See Bowen Declarations dated August 2001 at paragraphs 8-9 in the continuation patents of Liebowitz, which were submitted by Applicant). It should be noted, however, that these declarations were filed after the present application was filed. Moreover, the prosecution history of the Liebowitz continuation patents were not made public until they issued in January 2002, which was well after the filing date of the present application.

These results are significant in that the process by which a ribavirin composition is prepared markedly affects its manufacture. The flowability of a drug composition is an important manufacturing characteristic because it affects the weight variability of the drug in the dosage form, which in turns affects its dissolution and bio-availability in a subject having ingested the drug. Applicant describes these advantages in its specification at the bottom of page 1 and beginning of page 2.

Hence, it is respectfully submitted that the combination of cited art, and art known as of the filing date of the present application, would not have lead one of skill in the art to a process of preparing a ribavirin composition, with a likelihood of success, by adding a wetting agent or water thereto, as recited in claims 39-54 and 57-58.

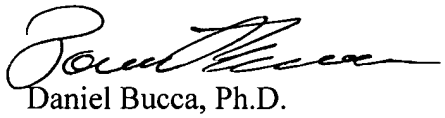
Moreover, Applicant respectfully submits that composition claims 55-56 which require free flowing ribavirin particles are patentable over Liebowitz based on, at least, the Bowen declaration submitted in Liebowitz.

Based on the forgoing, it is respectfully submitted that the claims in the application are patentable. Accordingly, reconsideration and allowance of the application are respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Daniel Bucca, Ph.D.
Registration No. 42,368

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 202.756.8000 DB:ajb
Facsimile: 202.756.8087
Date: August 23, 2006

Please recognize our Customer No. 20277 as our correspondence address.

Amendment to the Drawings:

The attached drawing sheet submitted herewith is one sheet of Formal Drawings in connection with the above referenced application.